No. 89-243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMICUS CURIAE THE AMERICAN ASSOCIATION OF RETIRED PERSONS IN SUPPORT OF RESPONDENT

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INTEREST OF THE AMICUS CURIAE

The American Association of Retired Persons ("AARP" or "the Association") is a not-for-profit membership organization operated exclusively for the social welfare of its 30 million members. It meets those members' diverse needs by providing a range of services including educational programs, informative publications, opportunities for volunteer service, special member benefits and discounts, as well as representation of the con-

cerns of older Americans before legislative, administrative and, where appropriate, judicial bodies.

AARP has long been an active proponent of legislation designed to increase public access to high quality, low cost health care. As such, the Association was actively involved in the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984.

The market for medical devices, and health care in general, is not precisely like any other. Because the consumption of health-care services, drugs and medical devices is usually not discretionary and because government directly pays for a large percentage of health-care services and goods, significant regulatory control over pricing and marketing inevitably exists.

Competitive forces do, nonetheless, play an important role in the development and availability of medical devices. Congress has long presumed that more competition would lead to lower prices and better products. That belief is at the center of this case.

AARP stands as a representative of millions of health-care consumers and older Americans who have a vital interest in maintaining access to the best and least costly medical devices. In this case, the interest of those consumers—and the express intent of Congress—will be vindicated only by affirmance of the lower court decision.

SUMMARY OF ARGUMENT

Both the patent laws and the Food, Drug and Cosmetic Act ("FDCA") are designed to benefit American consumers. The patent laws promote investment in research that results in innovation, while limiting the duration of monopoly power. The FDCA protects consumers from unsafe and ineffective medical drugs and devices by requiring governmental approval before new drugs and devices can be marketed. Together, the FDCA and the

patent laws work to ensure that scientific advances will be readily and safely available to Americans in need of medical services.

This case turns on the interplay between the patent laws and the FDCA and, like those laws generally, this case demonstrates Congress' desire to benefit consumer interests and "[o]lder Americans, in particular." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 17. In 1984, Congress recognized that a fundamental underpinning of the patent laws—the premise that all competitors have free and equal access to the marketplace—does not exist when the government delays market entry in order to ensure the safety and effectiveness of drugs and devices.

Section 271(e)(1) and Section 156 of the patent laws represent Congress' effort to ensure that all manufacturers of medical devices play by the same competitive rules. Patent holders are permitted an extension to ensure that their effective period of patent protection, and thus their incentive for research and innovation, is not impaired by regulatory delay imposed by the FDCA. Other competitors are permitted to test patented products during the patent period so that they will be ready to compete once the patent monopoly ends. That principle might be called the "market entry rule" because it ensures that the regulatory burden on market entry will not distort patent principles. The net effect of applying the rule to all market participants: The necessary FDA review for safety and effectiveness will not interfere with the competitive balance established by the patent laws and will, therefore, maintain the patent laws' primary goal of benefiting consumers.

The contrasting view—espoused by Lilly and its supporting *amici*—would apply this market entry rule to medical devices only part of the time and then only to the advantage of patent holders. It would permit the holder of a medical device patent to exclude competition not only for the length of an ordinary patent term, and

for an additional statutory term equal to the amount of time required to obtain FDA approval, but also for an additional, *de facto*, period while competitors attempt to test and secure FDA approval of their devices. Throughout this extended period consumers would be deprived both of the benefits of price competition for the original device and of innovations creating an improved version of the device.

Review of the express language, purpose and legislative history of Section 271(e)(1) demonstrates that the statute is not so narrow as Lilly contends. Thus, the lower court decision must be affirmed so that the intended beneficiaries of the Act—American consumers—receive the benefits of competitive innovation.

ARGUMENT

This *amicus* brief will not repeat the careful analysis of statutory language set forth in Medtronic's submission. Rather, AARP will focus on the structure and purpose of congressional action in order to show that Lilly's reading of congressional intent is unsupported. An accurate understanding of the policy goals implemented by Section 271(e)(1) demonstrates that Congress endeavored to create a level-playing field for all manufacturers of medical devices and, by so doing, to benefit the public. Because the starting point of statutory construction must be the language of the statute itself, this *amicus* brief will begin, however, with a brief discussion of the statutory words at issue here.

I. THE FEDERAL CIRCUIT'S DECISION WAS COMPELLED BY THE PLAIN LANGUAGE OF THE STATUTE

First, a line-by-line analysis of Section 271(e)(1) leaves no doubt that it applies to medical devices. In pertinent part, Section 271(e)(1) provides:

> It shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1).

The medical devices at issue are "patented invention[s]," *cf.* 35 U.S.C. § 100(a), that are regulated by the Food, Drug, and Cosmetic Act, *see* 21 U.S.C. § 351 *et seq.*, which is, as Section 271(e)(1) requires, "a Federal law which regulates the manufacture, use, or sale of drugs." *See id.*

Second, there is an obvious reason why Congress referred generally to "a Federal law which regulates . . . drugs" rather than specifically to the FDCA. In 1984, there were at least three federal laws which regulated the manufacture, use, or sale of drugs: the FDCA (which regulates certain drugs and devices); the Act of March 4, 1913, 21 U.S.C. §§ 151-58 (relating to viruses, serums, toxins, and analogous products intended for veterinary uses); and the Public Health Service Act of 1944, 42 U.S.C. § 262 (relating to viruses, serums, toxins, and analogous products intended for humans). *See also* Brief of *Amici Curiae* Zimmer, Inc. *et al.*, at 4 (Nov. 24, 1989). The reference to "a Federal law" simply indicates Congress' understanding that it was formulating a description applicable to more than one law.

Third, Lilly's interpretation of the phrase "a Federal law which regulates the manufacture, use, or sale of drugs" makes no sense. The phrase cannot, as argued, refer solely to 21 U.S.C. § 355, *see* Brief for the Petitioner at 10, because that section applies only to "new drug[s]," a category from which "new animal drug[s]" are excluded by definition. *See* 21 U.S.C. § 321(p). The *exception* for new animal drugs in section 271(e)(1) would have been unnecessary if section 271(e)(1) only applied,

in the first instance, to human drugs regulated under section 355.[1] The Lilly argument thus fails to construe the statute so as to give effect to all of its provisions. *See United States v. Menasche*, 348 U.S. 528, 538-39 (1955). The only reasonable conclusion is that "a federal law" refers to the FDCA and the previously cited Acts of 1913 and 1944.

II. SECTION 271(e)(1) IS PART OF A LEGISLATIVE PLAN DESIGNED TO TAILOR TRADITIONAL PATENT POLICIES TO THE REGULATORY CONTEXT IN WHICH MEDICAL DRUGS AND DEVICES ARE SOLD

Because the plain language leaves no doubt that Section 271(e)(1) applies to medical devices, the Court need look no further. *See United States v. James*, 478 U.S. 597, 606 (1986). Lilly, however, makes the additional argument that legislative policy would be contravened by applying Section 271(e)(1) to medical devices.

Lilly is wrong. An accurate understanding of the policy goals implemented by the 1984 Act demonstrates that Congress wished to establish a comprehensive scheme meshing patent and regulatory policies to assure consumers meaningful access to beneficial medical innovations that are safe and effective. This purpose can be achieved only if Section 271(e)(1) is applied to medical devices.

A. Congress Wished to Eliminate the Impact of Regulatory Delay on the Marketing of Medical Devices

The Drug Price Competition and Patent Term Restoration Act represents a carefully-crafted congressional

[1] As originally enacted, Section 271(e)(1) provided: "It shall not be an act of infringement to make, use, or sell a patented invention (*other than a new animal drug* or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1) (emphasis added).

response to the problem of applying traditional patent rules in a regulatory context. As the drafters of the Act were aware, federal patent law balances two competing values. On one hand, it encourages research and development by rewarding innovators with a statutorily-protected monopoly for a defined term of years. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 17. On the other hand, it encourages subsequent improvements and makes available the fruits of innovation to consumers by ending the statutory monopoly and allowing competition to enter the field. *Id.* at 46. The goal is to make the statutory monopoly long enough to encourage innovation adequately, but not so long as to delay the benefits of competition unnecessarily.

Because the patent laws presume free market entry, the period of patent protection is normally equal to the period of monopoly profit. Thus it is assumed that the patent holder will be able to profit from its invention from the inception of its patent term and that competitors will be able to move in as soon as the patent term expires.

In 1984, Congress recognized that market entry is restricted in a regulatory context. *First*, the original patent holder needs time to complete testing and obtain regulatory approval, so that the 17-year right to exclusive exploitation may permit many fewer years of monopoly profit—a period perhaps too short to reward innovation adequately. *Id.* at 17-18; H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. II at 6. *Second*, after the patent expires, competitors, not unlike the original patent holder, will need time to conduct testing and obtain regulatory approval of either an improved or a substantially identical version of the patented item, so that the benefits of competition may be delayed many years beyond the statutory right to exclusive exploitation. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 46.

Congress might have declined to act, hoping that the regulatory delays on each end of the patent term would cancel each other out, leaving a *de facto* term of monopoly profit fairly approximating the patent period. But Congress opted against leaving the competitive policies of the patent laws subject to the unpredictabilities of the FDA regulatory process. Instead, it applied a market entry rule to *both* ends of the patent term. *First*, the rule compensates the original innovator for any delay in market entry by allowing him to recover the amount of time required to obtain FDA approval at the end of his patent term. *See* 35 U.S.C. § 156. *Second*, the same rule is applied to competitors by permitting limited use of patented inventions in order to secure FDA approval, so that competition can begin immediately upon the termination of the patent. *See* 35 U.S.C. § 271(e)(1). In this way, the market entry rule guarantees that FDA regulation does not distort the competitive balance crafted by traditional patent principles. Consumers are thus served by the combination of three important policy goals: the development of new medical innovations, meaningful access to the new products, and protection from unsafe and ineffective products.

Accordingly, the 1984 Act modifies traditional patent law rules only to accommodate the realities of FDA regulation while leaving the underlying principles intact. This accommodation of competing values was not, as Lilly and its *amici* suggest, a mere trade-off among various elements of the drug industry, but a broader attempt to reconcile the policies of patent law with FDA regulation and to benefit the public through the increased availability of safe, effective, and innovative medical products.

B. Applying the New Scheme to Only Patent Holders of Medical Devices Would Distinguish Between Market Entrants in Violation of Congress' Clear and Explicit Intent

Lilly asks the Court to adopt an interpretation which would grant Lilly a benefit, but deny the corresponding benefit to its likely competitors.

Entities that hold patents to medical devices are clearly entitled to invoke the patent-term extension provisions of the Act. *See* 35 U.S.C. §§ 156(f)(1), 156(g)(3). Lilly itself has received the benefits of this provision through the extension of one of the patents at issue in the case. It is now asking this Court to grant it an additional *de facto* extension by barring innovators from experimentation until the patent term is over, thus potentially delaying for many years the commercial availability of a competing product.

No indication exists that Congress intended to favor some competitors with such a double patent extension, and every indication exists that it did not. As the statutory treatment of both drugs and veterinary products demonstrates, *see* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988), where Congress departs from the traditional concept of a 17-year right to exclusive exploitation, it does so only for the purpose of more carefully defining the underlying right to an effective, but strictly limited, term of monopoly profit. Granting Lilly's request would pervert this clearly expressed policy by providing patent holders with a windfall. More importantly, such an interpretation would run counter to the public policy of the patent laws by forcing consumers to suffer the burden of delay in market competition. The 1984 Act was an expression of Congress' explicit intent to relieve consumers of that burden.

The report of the House Committee on Energy and Commerce commenting on Section 156 states that

"[t]here should be no other direct or indirect method of extending patent term." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 46. Lilly's reading would create an indirect method of patent extension through an artificially narrow reading of Section 271(e)(1). To achieve the true congressional purpose, therefore, the lower court correctly read Section 271(e)(1) to apply along with Section 156 to medical devices.

C. Lilly's Arguments Based on the Differences Between Drugs and Medical Devices Are *Post Hoc* and Factually Incorrect

Lilly argues that differences in the regulatory schemes applicable to drugs and medical devices justify disparate treatment. Lilly focuses on 21 U.S.C. § 355(j), which provides that a generic version of an innovator drug may be approved for commercial marketing through an abbreviated process focusing primarily on whether the two drugs have the same rate and extent of absorption, a test that can often be made on healthy individuals.

Seizing on the existence of this abbreviated procedure, Lilly contends that drug testing will not impair the market of a patent holder even while the patent is in effect. But, Lilly contends, the testing of medical devices inevitably requires testing on the same individuals who would otherwise be using the patented product. From this Lilly concludes that Section 271(e)(1) is limited to drugs because, it is said, Section 271(e)(1) was not intended to permit testing on potential customers of the patent holder's product.

As an initial matter, the Lilly contention is beside the point because it was never made to Congress. No evidence exists in the legislative history that Congress was aware of a distinction in the regulatory schemes applicable to drugs and medical devices, much less of a distinction relevant to the meaning of Section 271(e)(1). Statutes cannot be interpreted on the basis of mere

assertions not presented to Congress at the time of enactment. *See United States v. Wise*, 370 U.S. 405, 411 (1962).

Aside from the fact that the argument was never presented to Congress, it is factually incorrect. Lilly misstates the scope of both drug and device testing, which are legally and factually quite similar.

Drug Testing. The FDA drug approval process may well require testing on the patent holder's potential customers. *See* 21 U.S.C. § 355(d). A drug manufacturer wishing to obtain approval of a drug that uses a patented drug but that varies one or more of the active ingredients may seek approval under the abbreviated process established by 21 U.S.C. § 355(j). However, "[i]f the FDA finds that safety and effectiveness testing of the active ingredients of the drug, individually or in combination, is required, then the FDA must deny the petition." H.R. Rep. No. 857, 98th Cong., 2d Sess. pt. I at 23. *See* 21 U.S.C. § 355(j)(3) In that case, the standard process of new drug approval must be used, which generally requires experimental proof that "the drug will have the effect it purports or is represented to have *under the conditions of use prescribed. . . .*" 21 U.S.C. § 355(d) (emphasis added). In other words, testing must be done on those suffering from the condition that the drug is designed to treat. *Cf.* 21 C.F.R. § 314.50(d)(2) (requiring the submission of results of *in vitro* studies of "the pharmacological actions of the drug in relation to its proposed therapeutic indication").

Even when the abbreviated process is available, ethical restrictions may require testing on potential customers of the patent holder. *See* 21 C.F.R. § 320.25(a)(3). Drugs with toxic side-effects, like AZT and certain cancer drugs, could not be given to persons who do not stand to benefit from the drug. *See also* Brief of *Amici Curiae* Zimmer, Inc. *et al.*, at 15 n.21 (Nov. 24, 1989).

Congress understood that drug testing could be a lengthy process. There would be little purpose to Section 271(e)(1) even as applied to drug testing if Congress had believed that all drugs could come to market quickly through an abbreviated process. Section 271(e)(1) exists precisely because Congress did not wish regulatory delay to create a *de facto* extension of the patent term. *See* text at pp. 9-10 *supra*. Thus, the first attempt to distinguish drug from device testing fails.

Medical Device Testing. Lilly's argument is even more overstated with regard to medical devices, the vast majority of which are tested under expedited procedures that, like the abbreviated process available for most generic drugs, do not eat into the market share of the patent holder. The FDCA groups medical devices into three categories. Class I devices are the least risky to human health and are subject to only general controls such as the requirement of sanitary packaging. *See* 21 U.S.C. §§ 360c(a)(1)(A), 351(a)(2). Class II devices are those of intermediate risk and thus are subject to FDA performance standards. *See* 21 U.S.C. §§ 360c(a)(1)(B), 360d. Finally, Class III devices, presenting the greatest risk to human health, are subject to an elaborate process of premarket review in which experimental proof of safety and efficacy is generally required. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e(d); 21 C.F.R. § 814.

The FDCA provides that devices introduced into interstate commerce after May 28, 1976, will generally be classified as Class III devices, and will therefore be subject to the premarket approval process. 21 U.S.C. § 360c(f)(1). However, a new device is exempted from the premarket approval process if it (i) is "within a type of device" that was on the market before May 28, 1976, or which has entered the market since then and has been classified as either Class I or II, and (ii) is "substantially equivalent to another device within such type." *Id. See also* 21 C.F.R. § 814.1(c)(1). In order to take

advantage of this exception, a device manufacturer need only submit a premarket notification setting forth information from which the FDA can determine 90 days before the device is marketed whether the device satisfies the substantial equivalence test. 21 U.S.C. § 360(k); 21 C.F.R. § 807.87.

The "substantial equivalence" process is in effect nothing more than a recognition that there are also "generic" medical devices. Under the FDCA, treatment of generic drugs and generic medical devices is similar because, in both circumstances, the premarket approval process is limited to the issue of whether the pioneer and the generic are really the same. "Well over 98 percent of the new [medical] devices that enter the market each year do so by claiming substantial equivalence, rather than going through premarket safety and effectiveness reviews." Medical Devices and Drug Issues: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 100th Cong., 1st Sess. 332 (1987). The percentage of new drugs that enter the market through the analogous streamlined process is virtually identical. *See id.* at 291. The prevalent use of the abbreviated process for medical devices thus disproves the second facet of Lilly's depiction of drug and device testing. The approval process for medical devices does not always—or even often—require testing on potential customers of the patent holder. Nonetheless, devices that are truly innovations—like the defibrillator Medtronic claims to be developing—must use lengthier approval procedures just as new drugs and certain generics must use the lengthier drug approval process. Thus, as Congress understood in 1984, FDA regulation and its impact on patent policy affects medical devices as it affects drugs. *See* H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 17.

The close similarity between the approval process for drugs and medical devices reinforces the conclusion that

Congress dealt with both by establishing in both cases a new "market entry" rule that applies equally to patent holders and their competitors.

III. THE LEGISLATIVE AND REGULATORY HISTORY SUPPORTS THE FEDERAL CIRCUIT'S INTERPRETATION OF SECTION 271(e)(1)

Against the language and purpose of Section 271(e)(1), Lilly relies on legislative history. For three reasons, however, that reliance is inadequate to show an intent to treat medical devices in a separate fashion.

First, Congress has always treated drugs and devices together. The original Food, Drug, and Cosmetic Act of 1938 contained a separate subchapter entitled "DRUGS AND DEVICES." June 25, 1938, c. 675, § 501, 52 Stat. 1049. That subchapter can be found today at 21 U.S.C. §§ 351-360ee, with the same title in place. Drugs and devices remain the only products regulated under that subchapter and, in fact, the first two sections of the subchapter, which bar consumer fraud, refer expressly to "drugs and devices." *See* 21 U.S.C. §§ 351 and 352. Because Congress gave no indication that it intended to sever this historical association of drugs and devices, the Court must presume that it continues in section 271(e)(1). *See, e.g., Moragne v. States Marine Line, Inc.*, 398 U.S. 375, 392 (1970) ("It has always been the duty of the common-law court to perceive the impact of major legislative innovations and to interweave the new legislative policies with the inherited body of common-law principles—many of them deriving from earlier legislative exertions.").

Second, Lilly argues, in support of its contrary reading of legislative history, that the brand name and generic drug industry trade associations were the most active advocates of the 1984 Act. But the accuracy of that assertion is, in the true evidentiary sense, irrelevant. Congressional intent is not found by surveying the prominence of private interests. Congress represents the public. The "compromise" embodied in Sections 156 and 271(e)(1) took place with the public interest in mind and serves that public interest—by applying the same market entry rule to all device manufacturers.

Third, the fact that the legislative history of Section 271(e)(1) fails to discuss medical devices does not suggest that they were meant to be excluded. *See Pittston Coal Group v. Sebben*, —— U.S. ——, 109 S. Ct. 414, 420-21 (1988) ("It is not the law that a statute can have no effects which are not explicitly mentioned in the legislative history. . . ."). Although the legislative history of the patent term restoration provision of Section 156 also focuses almost exclusively on drugs, all parties acknowledge Section 156 applies to medical devices as well.[2] That is because, in that circumstance as well as here, the express statutory language controls.

CONCLUSION

In sum, the Federal Circuit's decision is the only outcome that upholds the public policy of the patent laws to foster innovation for the benefit of society. This was Congress' goal in enacting the 1984 Act, and any other

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[2] For example, in its Summary of the Bill, the Judiciary Committee's report states: "The 'Drug Price Competition and Patent Term Restoration Act of 1984' (H.R. 3605) consists of two titles which affect introduction procedures and patent requirements for certain kinds of generic new *drugs*." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. II at 9 (emphasis added). The report continues: "Title II of the bill [which includes Sections 156 and 271(e)(1)] encourages *drug* manufacturers to assume the increased costs of research and development of certain products which are subject to premarketing clearance by restoring some of the time lost on patent life while the product is awaiting FDA approval." *Id.* (Emphasis added). By contrast, the report specifically mentions medical devices only in connection with a line-by-line analysis of Section 156. Thus, even where medical devices were expressly included within the statutory language, the narrative portions of the report referred only to drugs.

interpretation undermines that goal. The plain language of the statute, its underlying public policy, and the legislative and regulatory history all point to the same conclusion: The decision of the Federal Circuit must be affirmed.

For the foregoing reasons, the American Association of Retired Persons respectfully requests this Court to affirm the decision of the Federal Circuit.

Respectfully submitted,

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